The effect of dynaCleft® on presurgical orthopedics in bilateral cleft lip and palate patients

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Abstract

Aims: The aim of this study was to determine the effects DynaCleft® has on patients with bilateral cleft lip and palate. **Subjects and Methods:** Comparative data were collected from a total of 46 infants diagnosed with bilateral cleft lip and palate between 1981 and 2017. Twenty-three infants were treated with DynaCleft® and an obturator and 23 infants received an obturator only. Maxillary impressions were taken at each infant's initial clinic visit and again on the day of his/her surgical cleft lip repair. Differences in maxillary retraction, sagittal repositioning, and cleft widths were compared between the two groups. **Statistical Analysis Used:** Paired *t*-tests were used to determine if there was significant change before and after DynaCleft® therapy, and two-sample *t*-tests were used to compare the data between the two study groups. **Results:** Clinically, DynaCleft® averaged more maxillary retraction and cleft size reduction on both the right and left sides compared to the control group. Within the DynaCleft® group, a statistically significant difference was found for premaxillary retraction on both the right and left sides. However, all the other comparisons between the two groups were not found to be statistically significant. **Conclusions:** DynaCleft® as a presurgical orthopedic therapy may help to limit uncontrolled physiological changes and reposition the premaxillary segment, while reducing cleft widths prior to definitive lip surgery.

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Introduction

Craniofacial anomalies are a diverse group of congenital head-and-neck abnormalities, with the most common being a cleft lip, palate, or both, which can present as a unilateral or bilateral occurrence. In the United States, 1 in every 940 newborns is born with a cleft lip or palate, totaling over 4400 cases annually.[1] A bilateral cleft lip and palate is the least common form of the abnormality, resulting in only 0.3 of 1000 live births,[2] but it is one of the most challenging forms to treat due to a deficient columella and repositioning of the premaxillary segment in relation to the two clefts.[3] Treatment of the cleft lip and/or palate requires a team of dental and medical specialists, and starts as early as the first few months of life and continues through adulthood.[4] Comprehensive treatment for patients with bilateral cleft lip and palate typically consists of presurgical orthopedic (PSO) treatment and multiple surgeries throughout their lifetime, with continued postsurgery care by a pediatric and/or general dentist.[3] Patients with bilateral cleft lip and palate require a long-term commitment from the family and expenses that can exceed $100,000.[5]

PSO treatment involves the active movement of the maxillary segments with passive or active alveolar appliances prior to surgical repair.[6] The main goals of PSO are helping with intraoral feeding, improving maxillary growth, improving the projection of the nasal tip, reducing the nasal deformity, an adjunct in the primary lip, nasal, and alveolar surgeries, and retracting and repositioning the premaxilla more posteriorly and centrally located in patients with bilateral clefts.[6] In general, there are multiple clinical aspects that determine whether a patient needs PSO prior to surgery, and if so, what type should be used. Whether the cleft is complete, does the patient have feeding issues, and is the premaxilla protruded or off center are all aspects that should be considered.

The nasoalveolar molding (NAM) appliance, one method of presurgical therapy, helps to reduce the cleft size, correct nasal deformities and asymmetries, and lengthen the columella prior to the patient's first lip surgery. These attributes lead to a more esthetic and successful cleft repair outcome. However, because the NAM is a custom appliance, it requires multiple adjustments as the treatment progresses and the infant grows. Bilateral cleft lip and palate patients wearing the NAM appliance as a presurgical treatment may need up to twenty additional in-office visits prior to the initial lip surgery,[5] which may increase the time and financial burden for these families.

Lip adhesion surgery is another form of PSO undertaken prior to definitive lip closure. Lip adhesion is a surgical intervention that helps approximate the cleft segments and idealize nose position prior to final lip closure, requiring lip surgery to become a two-step process.[7] This additional procedure reconstructs a complete cleft into an incomplete cleft, which, in bilateral cleft patients, can help to control the protrusive premaxilla prior to definitive lip surgery. Although there are benefits to this procedure, it does require undergoing additional general anesthesia and there is an increased risk of lip dehiscence and scar tissue formation.[7]

DynaCleft® [Figure 1] is a premade adhesive device worn prior to cleft lip repair. It is a PSO with an elastomeric center which applies constant approximation forces that help mold the bone and soft tissues surrounding the clefts, as well as, create more nasal symmetry.[8] In cases of bilateral cleft patients, where the premaxillary segment between the two clefts can be significantly malpositioned, wearing DynaCleft® prior to lip surgery helps to reposition the segment. This can improve surgical results and decrease the need for lip adhesion surgery.[8] Unlike the NAM appliance, DynaCleft® does not require adjustments with growth of the infant,[8] which reduces the frequency of office visits and additional costs.[5]{Figure 1}

The purpose of this study was to determine the presurgical effects DynaCleft® has on patients with complete bilateral cleft lip and palate.

Subjects and Methods

This retrospective study was conducted at the craniofacial center of a metropolitan children's hospital and was approved by the institutional review board as study #1111007344. DynaCleft® was introduced and utilized as the standard of care at our craniofacial center for complete unilateral and bilateral cleft patients in January 2010. Data were collected from 46 infants

diagnosed with bilateral complete cleft lip and palate. The 46 patients were split into two groups of 23: one group was treated with DynaCleft® and the other was the control group who did not receive DynaCleft® therapy. All patients had maxillary alginate impressions taken at their initial presentation to clinic and then again on the day of their cleft lip repair. All the impressions were poured in dental stone. The treatment group received their DynaCleft® appliance at their initial appointment in the craniofacial clinic after being carefully evaluated by the craniofacial team which includes plastic and oral surgeons, as well as a pediatric dentist. After deemed an appropriate candidate for the therapy, the craniofacial clinic disperses the therapy at no cost to the patient via a grant from the Women for Riley/Riley Children's Foundation. A comprehensive demonstration on how to place the appliance and printed instructions for care were provided to all patients' caregivers. The control group patients were treated in the craniofacial clinic prior to the initiation of DynaCleft® therapy. All 46 patients had their initial impression taken around 1 month of age.

A predetermined set of points on the casts were used to measure the physiological changes that occurred between the two impressions for both groups: the right tuberosity (RT), left tuberosity (LT), incisal point (I), right alveolar crest (RA), left alveolar crest (LA), and the right premaxillary (RP) and left premaxillary (LP) segment points [Figure 2].[8]{Figure 2}

Dental casts for both groups were measured twice by the same individual with a Carrera Precision digital caliper (Max Tool LLC, LaVerne CA, USA) to ensure repeatability, and then the measurements were averaged and loaded into an Excel file. Intersegment distances were measured using the tuberosity and canine points. Intercleft distances were measured between the corresponding cleft side's premaxillary segment point and alveolar crest point as indicated by the RP-RA or LP-LA measurement. In addition, retraction of the premaxillary segment was determined by measuring the distance between the RT and LT and each premaxillary segment as indicated by RP-RT and LP-LT. Paired t-tests were used to determine if there was significant change before and after DynaCleft® therapy, and two-sample t-tests were used to compare the data between the two study groups.

Results

The DynaCleft® group had their first impression taken on an average at 19.4 days of age, with their follow-up impression taken on an average of 127.8 days later. The control group's first impression was taken on an average at 36.7 days of age, while their follow-up impression averaged 107.8 days later. Utilization of intraclass correlation coefficients and Bland–Altman plots determined all measurements to have excellent repeatability. No changes from initial visit to follow-up were significantly different between DynaCleft® and control groups [Table 1].{Table 1}

Discussion

This study was an attempt to assess the physiological effects of DynaCleft® on bilateral complete cleft lip and palate patients. In bilateral cleft lip and palate patients, the premaxillary segment that is separated by two clefts is usually not central and can protrude forward. DynaCleft®'s constant approximation forces pull the premaxillary segment back to a more anatomically correct location prior to surgery, which helps to centrally position the premaxilla and reduce cleft widths [Figure 3]. Although the data found no statistical significance between the two treatment groups for presurgical management of bilateral cleft lip and palates, they demonstrated that wearing DynaCleft® has clinical significance in restricting forward position and retracting the premaxillary segment, as well as reducing cleft sizes more so than the control group. The average changes from initial to follow-up measurements for the DynaCleft® group appear to be small, but with craniofacial surgeries, millimeters may affect the outcome and perhaps result in a more esthetic outcome. DynaCleft® can be utilized as a method of PSO therapy for bilateral cleft patients due to its ability to centralize and restrict forward displacement of the premaxillary segment and reduce cleft sizes, creating a more anatomically correct relationship for future cleft lip repair surgery.{Figure 3}

PSOs are widely used among craniofacial teams throughout the world. Critics believe that the added cost and increased office visits of these therapies do not outweigh the benefit they provide. They believe that the short-term effects do not significantly impact the long-term outcome of the cleft repair.[6] Garfinkle et al. found no difference between bilateral cleft patients who received PSOs and their noncleft, age-matched control group at 12 years of age.[9]

However, many craniofacial teams continue to use PSOs as an adjunct for treatment of cleft lip and palates. DynaCleft® is just

one of the several PSO options for families who lack the time and resources required for the NAM appliance or want to avoid additional anesthesia required for lip adhesion surgery. Without additional office visits, DynaCleft® provides the infant the benefits of prevention of forward growth and retraction of the premaxilla, as well as reducing cleft sizes prior to definitive lip surgery. Due to its elastomeric core and stretch property, DynaCleft® allows the infant to feed and cry without limitation. It also does not need to be remade or adjusted for infant growth like the NAM appliance.

There were some limiting factors to this study. At the initial delivery of DynaCleft®, the caregivers were demonstrated its proper placement and thoroughly explained when to replace each strip. The providers had to rely on the compliance of the caregivers to follow the provided instructions. Because our results are based on each patient's caregiver placing the therapy, this leads to increased variability. Other limitations to the study were the small sample size and the inability to control when each patient had their initial clinic visit and their surgical repair which would impact the results as each patient's DynaCleft® use period was not consistent.

Conclusions

The results of this study demonstrate that utilizing DynaCleft® as a method of PSO therapy may help limit anterior position and potentially centralize the clefted premaxillary segment to a more ideal location prior to surgery. Decreases in cleft widths were found among the bilateral cleft lip and palate patients who used DynaCleft®. The clinical attributes DynaCleft® provides are beneficial for craniofacial teams who choose to utilize PSOs for bilateral cleft lip and palate patients as part of their routine treatment plan.

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Conflicts of interest

There are no conflicts of interest.

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